REMARKS

The Amendment

Applicants have cancelled all pending claims and replaced same with claims 28-55. Applicants respectfully submit that the Amendment is made solely to avoid a statutory double patenting rejection over U.S. Patent No. 6,494,908, from which the present application claims priority. Applicants respectfully maintain that the claims pending prior to the Amendment are patentable over Murayama et al. (US Patent 6,423,085 B1), alone or in combination with D'Alessio, (US 5,674,286), as discussed herein below, and that the Amendment should not be construed in any way as acquiescing to the rejections set forth in the Office Action dated August 12, 2003.

The Invention

Applicants are claiming a relatively rigid stent for placement in a body lumen that, upon placement in the body, softens into a flexible state after an appropriate period of time such that it may be passed or removed easily from the body. The stent is a helical structure having a plurality of coils having a pitch. The stent is made from a first element comprising a filament having a cross-section and an outer surface. The filament prior to forming the helical structure comprises a soft, flexible elongated member having an outer surface. The stent comprises a second element in the form of a bioabsorbable or biodegradable polymeric coating on the outer surface of the helical structure. As such, Applicants' invention comprises two critical elements, those being the helical structure and the polymeric coating on the outer surface of the helical structure. The coating must have sufficient mechanical integrity to effectively maintain the previously flexible member in a relatively rigid helical configuration upon formation of such rigid configuration, and also must be degraded or absorbed in vivo in order to permit the rigid helical structure to revert to its soft, elongated structure after an appropriate time. As such, the stent is relatively rigid when placed in the body, and becomes soft and flexible in the body at the appropriate time to facilitate removal from the body. The coating must provide rigidity to the flexible member in the helical state until such time as removal of the member is desired.

The purpose of Applicants' invention is to temporarily maintain open passageways in a body lumen. Temporary stents avoid problems associated with permanent stents, as discussed at page 2, line 19 through page 3, line 11 of

Applicants' specification. Conventional temporary stents, however, also have issues related to premature material biodegradation, as described at page 4, lines 5-15 of Applicants' specification. Applicants have solved these problems by applying a coating to the outer coating of the stent that retains the mechanical integrity of the helical stent for a duration effective to accomplish the appropriate therapeutic purpose, while providing for enhanced, non-surgical removal. In this sense, Applicants respectfully submit that they have provided a novel and unobvious solution to a significant problem in the field of temporary stents.

Murayama

Murayama discloses intravasular devices that comprise at least in part a biodegradable and bioabsorbable polymer or protein that modify either accelerating or decreasing biological cellular response (Col. 3, ll 23-25). More particularly, according to Murayama, the biodegradable polymer must control thrombosis or accelerate wound healing of the brain aneurysms (Col. 4, ll 6-9). The biodegradable and absorbable polymer is said to comprise at least one polymer as set forth at Col. 3, ll 39-45. Beyond this generic disclosure, Murayama fails to provide any further guidance or description of biodegradable and absorbable polymers that may be used in devices disclosed therein. It is respectfully submitted that Murayama therefore fails to provide any guidance as to any properties of the coatings used therein that relate to the mechanical integrity of polymeric coatings.

35 U.S.C. 102(e)

Claims 1-4, 6, 7, 9, 12, 14-17, 19, 20, 22, 25 and 27 were rejected under 35 U.S.C. 102(e) as being anticipated over Murayama et al. US Patent 6,423,085 B1. Applicants respectfully disagree.

The Office Action states that "Murayama et al. discloses a biodegradable coil comprising a soft elongated member and a polymeric outer coating along the surface of the member." It further states that Murayama clearly discloses an implants having a filament made of fabric strands coated with a thrombin solution (Col. 2, lines 30-37), and that the thrombin coating may be enhanced by the addition of polymers as disclosed at col. 4, lines 26-31. Applicants respectfully disagree.

Initially, Applicants note that Col. 2, lines 30-37 disclose a coil that has had the surface area increased by the addition of fabric strands and that has been coated

with a thrombin solution. As such, Applicants submit that neither a helical structure nor a polymeric coating applied to the helical structure as claimed by Applicants is disclosed therein. Furthermore, Applicants respectfully submit that there is no indication or suggestion in Murayama that polymers as disclosed in the description of the invention for use in the Murayama devices would or should be incorporated with thrombin so as to provide a polymeric coating.

As expressly disclosed in Murayama, "In one embodiment, the coil is composed of a biocompatible and absorbable polymer or protein with a radio-opaque material disposed thereon. Alternately, the coil is composed of a radio-opaque material, and the biocompatible and absorbable polymer or protein is disposed thereon." (Col. 3, ll. 49-55). Where the coil is made of the bioabsorbable polymer, the radio-opaque material disposed thereon may be, e.g. tantalum or platinum (Col. 4, ll. 35-37). As such, Applicants respectfully submit that Murayama fails to disclose a device comprising both (a) a helical structure made from a soft, flexible elongated member having an outer surface and (b) a polymeric coating applied to the outer surface of the elongated member, where the polymeric coating provides mechanical integrity of the helical configuration, as claimed by Applicants. In fact, Applicants respectfully submit that Murayama only discloses device where, when the coil is made from an absorbable polymer, a radio-opaque material such as tantalum or platinum is disposed thereon; and where the coil comprises a bioabsorbable polymer or protein wrapped around the coil, the coil is a radio-opaque wire, e.g. platinum or nitinol (Col. 4, ll 35-39).

The standard for anticipation is on of strict identity. Applicants respectfully submit that Murayama fails to disclose or suggest a stent that comprises a relatively rigid helical structure made from a filament that initially is soft and flexible, and that upon placement in the body again becomes soft and flexible. Murayama further fails to disclose such a filament that has been coated with a polymer such that the polymer coating maintains the soft member in the relatively rigid helical structure and then degrades upon placement in the body such that the filament returns to its flexible state for easy passing or removal.

As Murayama fails to specifically disclose or describe any specific embodiments of devices disclosed therein, either by way of examples, formulations or drawings, Applicants respectfully submit that any rejections based on inherency as to specific embodiments claimed dependently by Applicants would be inappropriate.

Furthermore, as indicated at page 3, second paragraph of the Office Action, Murayama does not disclose a monofilament coil, a bioabsorbable filament, a transition temperature and a polymeric coating having polyamide. With respect to claims 2, 3, 15 and 16, Murayama fails to expressly disclose a melt or solution polymer, respectively. With respect to claims 4, 6, 7, 17, 19 and 20, Murayama fails to expressly disclose a suture as the elongated member. With respect to claims 6 and 19, Murayama fails to expressly disclose a multifilament suture as the elongated member, respectively. With respect to claims 7 and 20, Murayama fails to disclose a non-absorbable suture as the soft and flexible elongated member. As Murayama fails to disclose each element of the claim, Applicants respectfully submit that Murayama cannot anticipate any of the claims of the present invention.

Based on all of the foregoing, Applicants respectfully submit that Murayama fails to anticipate claims 1-4, 6, 7, 9, 12, 14-17, 19, 20, 22, 25 and 27.

Claims 5, 8, 10, 11, 13, 18, 21, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) over Murayama in view of D'Alessio, US 5,674,286. Applicants respectfully disagree.

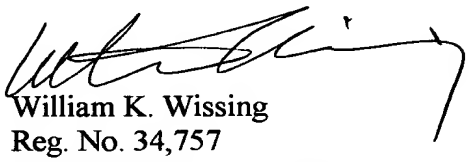
D'Alessio is directed to reinforced composite materials for use in, e.g. healing of fractured bones. Initially, Applicants respectfully submit that such materials are not suitable for placement in a body lumen and do not constitute relevant prior art with respect to either the present application or Murayama. Applicants respectfully submit that D'Alessio does not detach or suggest a coil of any kind. D'Alessio discloses a bundle of fibers comprising a plurality of reinforcement fibers and a matrix about those fibers formed from matrix fibers that have been softened so as to flow in and about the reinforcement fibers to form the matrix. Applicants respectfully submit that D'Alessio is silent as to any form of device that may be placed within a lumen of a body for the purpose of maintaining open passageways. As such, Applicants respectfully submit that the application of D'Allesio as prior art to the present invention is improper. Regarding the statement in the Office Action relating to claims 5 and 18, Applicants respectfully submit that Murayama does not disclose a yarn. Regarding claims 8 and 21, D'Allessio does not disclose absorbable sutures as implied by the Office Action. Regarding claims 10, 11, 23 and 24, D'Alessio refers to transition temperatures of polymers for the fibers, not polymers for coatings. In fact, D'Alessio does not disclose coatings of any kind. Regarding claims 13 and 26, while the Office Action states that the use of polyamides for inserting medical devices in a

body lumen is well know in the art, the Office Action fails to provide any basis for this statement or prior art to support this statement. Based on the foregoing, Applicant's respectfully submit that D'Alessio fails to cure any of the noted deficiencies of Murayama as noted above.

Accordingly, Applicants respectfully submit that Murayama in view of D'Alessio fail to render obvious any of the claims of the application under 35 U.S.C. 103(a).

Based on all of the foregoing, Applicants respectfully submit that all claims pending are patentable and earnestly request a Notice of Allowance to that affect.

Respectfully submitted,



William K. Wissing
Reg. No. 34,757
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6201